510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

k200403

B Applicant

Nova Biomedical Corporation

C Proprietary and Established Names

Stat Profile® Prime Plus Analyzer System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JGS	Class II	21 CFR 862.1665 - Sodium Test System	CH - Clinical Chemistry
JFP	Class II	21 CFR 862.1145 - Calcium test system	CH - Clinical Chemistry
CEM	Class II	21 CFR 862.1600 - Potassium test system	CH - Clinical Chemistry
CGZ	Class II	21 CFR 862.1170 - Chloride test system	CH - Clinical Chemistry
CFA	Class I, reserved	21 CFR 862.1495 - Magnesium test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification of a previously cleared device (k180428) – modify the intended use of the device to include Point-of-Care (POC) use.

B Measurand:

Sodium (Na), Potassium (K), Chloride (Cl), Ionized Calcium (iCa) and Ionized Magnesium (iMg)

C Type of Test:

Quantitative, potentiometric, ion selective electrode

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Stat Profile® Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of Sodium, Potassium, Chloride, Ionized Calcium, and Ionized Magnesium in heparinized arterial and venous whole blood.

Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.

Potassium measurements are used in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Ionized calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Ionized magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium).

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For clinical laboratory and point of care use.

D Special Instrument Requirements:

Stat Profile® Prime Plus Analyzer System

IV Device/System Characteristics:

A Device Description:

The Stat Profile® Prime Plus Analyzer System is a small automatic blood gas analyzer for laboratory and point of care setting. It consists of the analyzer, sensor cartridges, calibrator packs, auto-cartridge quality control packs (internal controls), ampuled quality control materials (external controls) and thermal paper for an onboard printer. Specimens may be identified by scanning a barcode or by manually entering the information via the touchscreen.

The Stat Profile® Prime Plus Analyzer has slots to accommodate two sensor cartridges (Primary and Auxiliary). The analyzer will determine the configuration of the system by detecting which sensor cards are installed. The reporting of CO-Oximeter parameters (or not reporting them) will also be determined by the selection of the Sensor Cards, for which there are two options:

- Primary Sensor Card 1 reports the following analytes: pO_2, pCO_2, pH, Hct, tHb, Na, Cl, K, iCa, iMg, Glu, SO_2, O_2Hb, COHb, MetHb, HHb, tBil, HbF
- Primary Sensor Card 2 reports the following analytes: pO_2, pCO_2, pH, Hct, tHb, Na, Cl, K, iCa, iMg, Glu, SO_2.

B Principle of Operation:

The sodium, potassium, chloride, ionized calcium and ionized magnesium parameters are measured by an ion-selective electrode (ISE) that selectively measures the activity of ionic species. When the ISE is contacted with a sample, a potential is developed. The potential is proportional to the logarithm of the ionic activity and is measured versus a reference electrode, as described by the Nernst equation.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Stat Profile® Prime Plus Analyzer System

B Predicate 510(k) Number(s):

k180428

C Comparison with Predicate(s):

Device & Predicate Device(s):	k200403	k180428
Device Trade Name	Stat Profile® Prime Plus Analyzer	Stat Profile® Prime Plus Analyzer
General Device Characteristic Similarities		
Intended Use/Indications For Use	For in vitro diagnostic use for the determination of sodium, potassium, chloride, ionized calcium and ionized magnesium in heparinized arterial and venous whole blood	Same
Acceptable Sample Types	Lithium heparin venous and arterial whole blood from syringes and open tubes	Same
Sample Volume	135 µL	Same
General Device Characteristic Differences		
Settings for Use	Clinical laboratories and point-of-care settings	Clinical laboratories

VI Standards/Guidance Documents Referenced:

IEC 61010-1:2010 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements.

IEC 60601-1-2:2014 – Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Three separate studies were conducted to evaluate the precision of Stat Profile® Prime Plus Analyzer the for Na, K, Cl, iCa and iMg. The studies were conducted at three point-of-care (POC) sites including a Cardiothoracic Intensive Care Unit, an Emergency Department and a

Respiratory Therapy Lab. A total of 61 respiratory care, 12 nursing, and 1 exercise physiology POC personnel participated from the 3 POC settings over the course of the studies.

a) Within-Run Precision using controls

Within-run precision of the Stat Profile® Prime Plus Analyzer System in the hands of POC operators was assessed using QC levels of Quality Control (QC) materials and one level of linearity material (LN) to cover the measuring range for each analyte. Each sample was analyzed in replicates of 20 using three Stat Profile® Prime Plus Analyzer Systems. All three POC sites produced similar results. Representative within-run precision results from one site are summarized in the table below:

Within Run Precision - one representative POC site

Analyte	N=20	QC Level 4	LN Level 1	LN Level 4
Na^+ (mmol/L)	Mean	137.1	90.8	170.8
	SD	0.3	1.0	0.4
	% CV	0.2	1.0	0.2
K^+ (mmol/L)	Mean	3.93	1.69	11.83
	SD	0.04	0.03	0.06
	% CV	1.1	1.8	0.5
Cl^- (mmol/L)	Mean	122.9	61.1	132.8
	SD	0.4	1.1	0.4
	% CV	0.4	1.8	0.3
iCa^{2+} (mmol/L)	Mean	1.06	2.28	0.47
	SD	0.02	0.02	0.00
	% CV	1.6	0.9	1.0
iMg^{2+} (mmol/L)	Mean	0.61	1.27	0.24
	SD	0.01	0.04	0.00
	% CV	1.0	3.4	1.4

b) Total Imprecision using controls

Total imprecision of the Stat Profile® Prime Plus Analyzer System in the hands of POC operators was assessed using three levels of QC materials/Linearity materials, three Stat Profile® Prime Plus Analyzer Systems and four different lots of calibration cartridges. For each run, each sample was run in duplicate each day for a total of 20 days (a total of 40 replicates per sample). All three POC sites produced similar results. Representative total imprecision results from one site are summarized in the table below:

Total Imprecision – one representative POC site

Analyte	N	Mean	Within Run SD	Within Run %CV	Total SD	Total %CV
QC Level 4						
Na^+ (mmol/L)	40	136.7	0.5	0.4	0.5	0.4
K^+ (mmol/L)	40	3.90	0.05	1.2	0.07	1.9
Cl^- (mmol/L)	40	95.0	0.5	0.5	0.7	0.7
iCa^{2+} (mmol/L)	40	1.06	0.04	3.8	0.04	3.8
iMg^{2+} (mmol/L)	40	0.60	0.02	2.9	0.03	5.5

Analyte	N	Mean	Within Run SD	Within Run %CV	Total SD	Total %CV
QC Level 5						
Na^+ (mmol/L)	40	109.9	0.4	0.4	0.6	0.5
K^+ (mmol/L)	40	6.35	0.07	1.0	0.09	1.5
Cl^- (mmol/L)	40	95.0	0.4	0.4	0.6	0.6
iCa^{2+} (mmol/L)	40	1.52	0.08	5.3	0.10	6.8
iMg^{2+} (mmol/L)	40	1.08	0.03	3.1	0.06	5.7
LN Level 4						
Na^+ (mmol/L)	40	169.7	0.6	0.3	0.6	0.3
K^+ (mmol/L)	40	12.15	0.07	0.6	0.11	0.9
Cl^- (mmol/L)	40	133.0	0.7	0.5	1.4	1.0
iCa^{2+} (mmol/L)	40	0.46	0.00	1.0	0.01	1.1
iMg^{2+} (mmol/L)	40	0.25	0.02	7.7	0.02	7.9

c) Precision using whole blood samples

A whole blood within-run precision study was performed at three POC sites by a total of nine POC operators using three Stat Profile® Prime Plus Analyzer Systems (one at each site). Five different native venous samples and two altered venous samples were analyzed in replicates of 10 at each site. The results from each site are presented in the tables below.

Point-of-care site 1

Analyte	Sample	N	Mean	SD	%CV
Na^+ (mmol/L)	1	10	141.8	0.49	0.35
	2	10	140.6	0.41	0.29
	3	10	134.5	0.31	0.23
	4	10	135.4	0.29	0.21
	5	10	134.5	0.36	0.26
	6 (altered)	10	133.7	0.36	0.27
	7 (altered)	10	139.3	0.27	0.19
K^+ (mmol/L)	1	10	4.0	0.03	0.69
	2	10	4.3	0.02	0.45
	3	10	3.7	0.01	0.36
	4	10	2.9	0.02	0.81
	5	10	3.8	0.02	0.40
	6 (altered)	10	8.56	0.15	1.73
	7 (altered)	10	7.45	0.06	0.80
Cl^- (mmol/L)	1	10	104.0	0.47	0.45
	2	10	105.1	0.57	0.54
	3	10	99.8	0.63	0.63
	4	10	107.5	0.53	0.49
	5	10	101.4	0.52	0.51
	6 (altered)	10	103.1	0.57	0.55
	7 (altered)	10	105.4	0.70	0.66
iCa^{2+} (mmol/L)	1	10	1.30	0.01	0.80
	2	10	1.29	0.01	0.68
	3	10	1.42	0.01	0.49

Analyte	Sample	N	Mean	SD	%CV
	4	10	1.23	0.01	0.46
	5	10	1.20	0.01	0.53
	6 (altered)	10	1.24	0.01	0.68
	7 (altered)	10	1.28	0.01	0.72
iMg^{2+} (mmol/L)	1	10	0.64	0.02	2.87
	2	10	0.61	0.00	0.79
	3	10	0.71	0.01	0.75
	4	10	0.51	0.01	1.40
	5	10	0.65	0.01	0.98
	6 (altered)	10	0.58	0.00	0.81
	7 (altered)	10	0.58	0.01	1.16

Point-of-care site 2

Analyte	Sample	N	Mean	SD	%CV
Na^{+} (mmol/L)	1	10	123.7	0.82	0.67
	2	10	138.2	0.42	0.31
	3	10	141.1	0.32	0.22
	4	10	142.9	0.57	0.40
	5	10	137.9	0.32	0.23
	6 (altered)	10	133.6	0.70	0.52
	7 (altered)	10	138.3	0.67	0.49
K^{+} (mmol/L)	1	10	4.71	0.03	0.67
	2	10	1.94	0.05	2.66
	3	10	4.02	0.04	1.05
	4	10	4.11	0.03	0.77
	5	10	3.30	0.00	0.00
	6 (altered)	10	3.73	0.05	1.30
	7 (altered)	10	7.91	0.09	1.11
Cl^{-} (mmol/L)	1	10	88.6	0.52	0.58
	2	10	116.8	0.63	0.54
	3	10	103.8	0.42	0.41
	4	10	103.0	0.00	0.00
	5	10	109.1	0.32	0.29
	6 (altered)	10	104.4	0.70	0.67
	7 (altered)	10	109.6	0.52	0.47
iCa^{2+} (mmol/L)	1	10	1.24	0.01	0.43
	2	10	0.75	0.01	1.13
	3	10	1.28	0.01	0.40
	4	10	1.31	0.01	0.54
	5	10	0.98	0.01	0.52
	6 (altered)	10	1.13	0.01	0.95
	7 (altered)	10	1.22	0.01	0.61
iMg^{2+} (mmol/L)	1	10	0.56	0.01	1.50
	2	10	0.31	0.01	2.63
	3	10	0.61	0.00	0.52
	4	10	0.62	0.01	1.02

Analyte	Sample	N	Mean	SD	%CV
	5	10	0.46	0.00	0.91
	6 (altered)	10	0.48	0.01	2.29
	7 (altered)	10	0.58	0.01	0.98

Point-of-care site 3

Analyte	Sample	N	Mean	SD	%CV
Na^+ (mmol/L)	1	10	118.8	0.42	0.35
	2	10	143.8	0.42	0.29
	3	10	140.1	0.32	0.23
	4	10	134.2	0.42	0.31
	5	10	133.0	0.00	0.00
	6 (altered)	10	134.0	0.00	0.00
	7 (altered)	10	139.1	0.57	0.41
K^+ (mmol/L)	1	10	7.0	0.05	0.69
	2	10	4.1	0.04	1.03
	3	10	4.1	0.04	1.02
	4	10	4.0	0.00	0.00
	5	10	3.5	0.00	0.00
	6 (altered)	10	8.43	0.07	0.80
	7 (altered)	10	8.35	0.22	2.66
Cl^- (mmol/L)	1	10	92.5	0.53	0.57
	2	10	104.2	0.42	0.40
	3	10	107.5	0.53	0.49
	4	10	102.0	0.00	0.00
	5	10	97.0	0.00	0.00
	6 (altered)	10	103.1	0.88	0.85
	7 (altered)	10	104.9	0.57	0.54
iCa^{2+} (mmol/L)	1	10	1.14	0.005	0.46
	2	10	1.33	0.004	0.32
	3	10	1.25	0.00	0.00
	4	10	1.57	0.01	0.40
	5	10	1.51	0.01	0.76
	6 (altered)	10	1.26	0.01	0.54
	7 (altered)	10	1.27	0.01	0.85
iMg^{2+} (mmol/L)	1	10	0.54	0.00	0.90
	2	10	0.60	0.01	0.85
	3	10	0.58	0.00	0.00
	4	10	0.66	0.01	1.02
	5	10	0.67	0.01	1.43
	6 (altered)	10	0.57	0.00	0.55
	7 (altered)	10	0.56	0.00	0.57

2. Linearity:

Previously established in k180428.

3. Analytical Specificity/Interference:

Previously established in k180428.

4. Assay Reportable Range:

Previously established in k180428.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Previously established in k180428.

6. Detection Limit:

Previously established in k180428.

Analyte	Measuring range (mmol/L)
Na^+	80 - 200
K^+	1.0 - 20.0
Cl^-	50 - 200
iCa^{2+}	0.1 - 2.7
iMg^{2+}	0.1 - 1.5

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison studies were conducted at three POC sites - a Cardiothoracic Intensive Care Unit, an Emergency Department and a Respiratory Therapy Lab. Lithium heparinized arterial and venous whole blood specimens were analyzed in singlet using three Stat Profile® Prime Plus analyzers (one at each site) by 65 POC staff members (13, 21 and 31 POC staff members within each testing site, respectively, including a total of 52 respiratory care, 12 nursing, and 1 exercise physiology POC personnel). In order to cover the claimed measuring range for each analyte, less than 10% of samples for each analyte were altered. The clinical results obtained by POC staff members were compared to results obtained by trained healthcare professionals from the same whole blood specimens. Each of the three sites produced similar method comparison data. Linear regression analysis for venous and arterial whole blood method comparison for all POC sites combined is presented in the table below.

Venous and arterial whole blood method comparison – POC vs. Laboratory Operators (combined sites)

Analyte	N	Sample concentration range	Slope	Intercept	r
Na^+ (mmol/L)	432	90.0 – 187.0	0.9964	0.4488	0.9949

Analyte	N	Sample concentration range	Slope	Intercept	r
K^+ (mmol/L)	435	1.10 – 17.60	1.0158	-0.0678	0.9993
Cl^- (mmol/L)	434	56.0 – 173.0	0.9963	0.4416	0.9971
iCa^{2+} (mmol/L)	434	0.51 – 2.48	0.9820	0.0239	0.9871
iMg^{2+} (mmol/L)	426	0.24 – 1.36	1.0020	-0.0021	0.9910

2. Matrix Comparison:

   Not applicable. The only acceptable sample type for this device is lithium heparin whole blood.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Previously established in k180428.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.